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Midterm results of adjunctive neck therapies performed during elective infrarenal aortic aneurysm repair

Jayer Chung, Matthew A. Corriere, Ross Milner, Karthikeshwar Kasirajan, Atef Salam, Thomas F. Dodson, Elliott L. Chaikof, Ravi Kumar Veeraswamy

Objective: This study evaluated the durability of adjunctive endovascular neck procedures, including aortic cuffs, Palmaz stents (Cordis, Miami Lakes, Fla), and high-pressure balloon angioplasty, at managing intraoperative proximal neck complications during endovascular aortic aneurysm repair (EVAR).
Methods: This was a single-center retrospective review of EVARs. The primary outcome variable studied was survival free of a graft-related event (GRE). GRE was defined by the occurrence of one of the following: type I endoleak, sac enlargement, aneurysm rupture, death, or procedure related to the aortic neck. These outcome variables were assessed relative to the preoperative anatomic neck variables (neck length, diameter, degree of angulation, degree of circumferential thrombus, and presence of conicity), procedural variables (manufacturing type of graft, use of a Palmaz stent), and patient characteristics (age and presence of medical comorbidities). Outcomes were assessed by *t* tests, Pearson χ^2, **and Kaplan-Meier analysis, when appropriate.**
Results: A total of 174 EVARs performed between January 2005 and December 2007 were evaluated. Fifty-six adjunctive procedures were performed, with a 97% primary-assisted exclusion rate. Patients who received an adjunctive therapy had similar freedom from a GRE compared with EVARs that did not require adjunctive therapy (35.5 $\pm$ 2.6 vs 34.8 $\pm$ 1.5 months, P = .31, log-rank test). Subset analysis identified a significant association between Palmaz stent placement at the time of EVAR and decreased freedom from GREs (hazard ratio, 2.87; 95% confidence interval, 1.21-6.77; P = .02).
Conclusions: Midterm results suggest that adjunctive therapies to manage intraoperative proximal neck complications do not compromise durability. The subset of patients requiring aortic neck Palmaz stent placement at the time of EVAR are among those at highest risk for subsequent GRE.

First United States experience of the TX2 Pro-Form thoracic delivery system

W. Anthony Lee, Tomas D. Martin, Philip J. Hess Jr, Thomas M. Beaver, Charles T. Klodell

Objectives: Failure to conform to the arch (''bird-beaking'') can lead to endoleak and graft collapse after thoracic endovascular aortic repair (TEVAR). We report the first United States experience with the new TX2 Pro-Form (Cook Inc, Bloomington, Ind), a novel delivery system that became commercially available in October 2009, designed to enhance circumferential apposition of the TX2 thoracic endograft to the arch.
Methods: This was a single-institution retrospective study. Endograft-to-arch conformance was quantitatively analyzed using intraoperative angiograms of consecutive, reverse chronologic cohorts of TX2 Pro-Form, TX2 Z-Trak (prior delivery system; Cook), and Gore TAG (W.L. Gore and Assoc, Flagstaff, Ariz). Only native aortic arch deployments in zones 2 and 3 were included.
Results: During a 6-week period, 20 Pro-Form cases were performed, of which 17 patients met inclusion criteria. These were compared with 17 Z-Trak and 17 TAG patients. Endografts were successfully delivered to their intended proximal landing zones in all 51 patients. A higher proportion of dissections were treated in the Z-Trak (65%) and TAG (76%) patients (P = .03), but similar rates of zone 2/3 deployments (P = .30). Despite the mean arch angle being greatest for the Pro-Form patients (90° vs 74° vs 71°, P = .18), the mean separation between the leading endograft edge and the aortic wall along the inner curvature of the arch was significantly less (1.4 vs 4.1 vs 5.7 mm; P = .0002), with complete apposition achieved in 65% of Pro-Form patients (18% Z-Trak, 6% TAG, $P < .0001$). This resulted in the lowest reduction in aortic luminal diameter at the proximal landing zone (5.5% vs 13.4% vs 19.3%; P = .0006) compared with Z-Trak and TAG. Rates of type Ia endoleak were similar (P = .38).
Conclusions: The Pro-Form delivery system significantly improves endograft conformation to the arch, resulting in minimum bird-beaking even in severely angulated anatomies.

Outcomes before and after initiation of an acute aortic treatment center

Mark G. Davies, Houssam K. Younes, Patricia W. Harris, Faisal Masud, Bryan A. Croft, Michael J. Reardon, Alan B. Lumsden

Background: Acute aortic syndromes remain life-threatening. Time is of the essence, as mortality rises with increasing time after the acute episode. The aim of this report is to show changes in practice and outcomes after the establishment of an acute aortic treatment center (AATC) to expedite the care of acute aortic syndromes in a major metropolitan area with the belief that ''door to intervention time under 90 minutes'' reduces mortality and morbidity from acute aortic disease.
Methods: A database of patients admitted with acute aortic disease (Type A and B aortic dissections, acute thoraco-abdominal aortic aneurysms, acute and ruptured abdominal aortic aneurysms) for 1 year prior to initiation (2007) and 1 year after initiation of the pathway (AATC) in 2008 was developed. Comorbidities were scored according to Society of Vascular Surgery criteria. Anatomic and functional outcomes were determined and categorized by Society of Vascular Surgery reporting criteria. Multivariate analysis was performed for categorical outcomes and Cox proportional hazard analyses for time-dependent outcomes.
Results: Six hundred twenty-one patients reported with aortic disease to the cardiovascular services; 306 patients were considered to have acute disease. When compared with the year before the AATC was instituted, there was a 30% increase in the total number of admissions and a 25% increase in acute pathology after setting up the AATC (P = .02). There was a two-fold increase in thoracic aortic dissections admitted to the

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service. Initiation of the treatment pathway resulted in a highly significant 64% reduction in time to definitive therapy (526 ± 557 vs 187 ± 258 minutes, mean ± SD pre-AATC vs AATC; P = .0001). Comorbidity scores were equivalent between the two cohorts. Despite the increase in acuity, mortality (4% vs 6%) and morbidity (41% vs 45%) rates were unchanged, and there was a significant decrease in intensive care unit length of stay (5 vs 4 days, pre-AATC cohort vs the AATC cohort), but total hospital length of stay (11 vs 10 days) was unchanged. There was no correlation between deaths within 30 days and length of stay in the intensive care unit.

Conclusion: Establishment of a multidisciplinary AATC pathway was associated with a 30% increase in volume, 64% reduction in time to definitive treatment, improved throughput with reduced intensive care unit time, and maintained clinical efficacy despite an increase in acute admissions. These results suggest the concept be further evaluated.

Eight-year experience with carotid artery stenting for correction of symptomatic and asymptomatic post-endarterectomy defects

Enrico Maria Marone, Giovanni Coppi, Yamume Tshomba, Roberto Chiesa

Background: Carotid endarterectomy (CEA) has been shown to be superior to medical therapy alone in the prevention of stroke only if it can be safely performed (ie, with a complication rate less than 3% in asymptomatic patients and less than 6% in symptomatic patients). Technical defects are the most common cause of neurological complications after CEA, and their correction has traditionally been performed through standard surgical techniques.

Methods: From 1999, we started to treat intimal flaps, dissection, or partial thrombosis after CEA with carotid artery stenting (CAS). A retrospective analysis of the operating room registry and of the registry of our Interventional Cardiology laboratory was conducted in order to identify all the patients that underwent stenting of the internal carotid artery after CEA between January 2001 and June 2009.

Results: During the time period considered, 5012 CEA were performed at our institution and a total of 34 patients (34/5012; 0.6%) were found to have received carotid stenting after CEA, both for symptomatic and asymptomatic defects. Immediate technical success was obtained in all patients. One major cerebrovascular adverse event (1/34; 3%) in the immediate perioperative period was recorded. At a mean follow-up of 18.6 months (range, 3-84 months; median, 12 months), we did not observe any neurological symptoms related to the treated carotid artery, nor hemodynamic in-stent restenosis. Long-term follow-up (ie, equal or greater than 4 years) was available for five patients: all patients remained event-free during the entire period.

Conclusions: Our study adds to the assumption that CAS in post-CEA symptomatic and asymptomatic patients is safe and technically feasible, and represents a valid and quick alternative to standard surgical revision. Even if in a small group of patients, long-term results seem promising.

Important observations made managing carotid body tumors during a 25-year experience

Allan J. Kruger, Philip J. Walker, Wallace J. Foster, Jason S. Jenkins, Nicholas S. Boyne, Julie Jenkins

Objectives: Our objective was to assess the short-term and long-term outcome for patients after carotid body tumor (CBT) resection and discuss the potential pitfalls of the treatment.

Methods: An analysis was undertaken of all patients who underwent CBT resection at Royal Brisbane and Women's Hospital and Greenslopes Private Hospital between 1982 and 2007. Primary tumor characteristics, surgical technique, and outcomes were recorded and analyzed.

Results: A total of 49 consecutive CBT resections (2 recurrent tumors) were carried out in 39 patients (26 women [56%]) who were a mean age of 49 years (range, 17-75 years). A nontender neck mass was the presenting complaint in 85%, followed by screening in familial or contralateral tumors in 26%. Familial cases occurred in 11 patients (28%). There were no operative deaths. Complications occurred in 13 of the 49 operations (27%), predominantly temporary nerve palsies, and were more likely to occur in tumors of large volume or in cases of removal of coexisting vagal tumors. Malignant disease was present in seven cases (15%). All patients have been followed-up postoperatively for a mean of 11 years (range, 2-26 years). Metachronous paragangliomas have been discovered in six patients, all with familial disease.

Conclusions: Early resection of carotid body tumors should be undertaken while still small to minimize the risk of neural injury, which increases with tumor size. In cases of bilateral CBT, we recommend that the smaller tumor be resected first, before the staged resection of the larger contralateral tumor. In familial or bilateral tumor cases, other synchronous and metachronous paragangliomas should be excluded. Mandatory lifelong follow-up is essential.

Safety and efficacy of patient specific intramuscular injection of HGF plasmid gene therapy on limb perfusion and wound healing in patients with ischemic lower extremity ulceration: Results of the HGF-0205 trial

Richard J. Powell, Phillip Goodney, Farrell O. Mendelsohn, Elaine K. Moen, Brian H. Annex

Objectives: We have previously reported the results of a dose-finding phase II trial showing that HGF angiogenic gene therapy can increase TcPO2 compared with placebo in patients with critical limb ischemia (CLI). The purpose of this randomized placebo controlled multi-center trial was to further assess the safety and clinical efficacy of a modified HGF gene delivery technique in patients with CLI and no revascularization options.

Methods: Patients with lower extremity ischemic tissue loss (Rutherford 5 and 6) received three sets of eight intramuscular injections every 2 weeks of HGF plasmid under duplex ultrasound guidance. Injection locations were individualized for each patient based on arteriographically defined vascular anatomy. Primary safety end-point was incidence of adverse events (AE) or serious adverse events (SAE). Clinical endpoints included change from baseline in toe brachial index (TBI), rest pain assessment by a 10 cm visual analogue scale (VAS) as well as wound healing, amputation, and survival at 3 and 6 months.

Results: Randomization ratio was 3:1 HGF (n = 21) vs placebo (n = 6). Mean age was 76 ± 2 years, with 56% male and 59% diabetic. There was no difference in demographics between groups. There was no difference in AEs or SAEs, which consisted mostly of transient injection site discomfort, worsening of CLI, and intercurrent illnesses. Change in TBI significantly improved from baseline at 6 months in the HGF-treated group compared with placebo (0.05 ± 0.05 vs −0.17 ± 0.04; P = .047). Change in VAS from baseline at 6 months was also significantly improved in the HGF treated group compared with placebo (−1.9 ± 1.3 vs +0.06 ± 0.2; P = .04). Complete ulcer healing at 12 months occurred in 31% of the HGF group and 0% of the placebo (P = .28) There was no difference in major amputation of the treated limb (HGF 29% vs placebo 33%) or mortality at 12 months (HGF 19% vs placebo 17%) between groups.

Conclusion: HGF gene therapy using a patient vascular anatomy specific delivery technique appears safe, maintained limb perfusion, and decreased rest pain in patients with CLI compared with placebo. A larger study to assess the efficacy of this therapy on more clinically relevant end points is warranted.

Cost-effectiveness of guidelines for insertion of inferior vena cava filters in high-risk trauma patients

Emily L. Spangler, Ellen D. Dillavou, Kenneth J. Smith

Background: Inferior vena cava filters (IVCFs) can prevent pulmonary embolism (PE); however, indications for use vary. The Eastern Association for the Surgery of Trauma (EAST) 2002 guidelines suggest prophylactic IVCF use in high-risk patients, but the American College of Chest Physicians (ACCP) 2008 guidelines do not. This analysis compares cost-effectiveness of prophylactic vs therapeutic retrievable IVCF placement in high-risk trauma patients.

Methods: Markov modeling was used to determine incremental cost-effectiveness of these guidelines in dollars per quality-adjusted life-years (QALYs) during hospitalization and long-term follow-up. Our population was 46-year-old trauma patients at high risk for venous thromboembolism (VTE) by EAST criteria to whom either the EAST (prophylactic IVCF) or ACCP (no prophylactic IVCF) guidelines were applied. The analysis

assumed the societal perspective over a lifetime. For base case and sensitivity analyses, probabilities and utilities were obtained from published literature and costs calculated from Centers for Medicare & Medicaid Services fee schedules, the Healthcare Cost & Utilization Project database, and *Red Book* wholesale drug prices for 2007. For data unavailable from the literature, similarities to other populations were used to make assumptions.

Results: In base case analysis, prophylactic IVCFs were more costly ($37,700 vs $37,300) and less effective (by 0.139 QALYs) than therapeutic IVCFs. In sensitivity analysis, the EAST strategy of prophylactic filter placement would become the preferred strategy in individuals never having a filter, with either an annual probability of VTE of $\geq$9.6% (base case, 5.9%), or a very high annual probability of anticoagulation complications of $\geq$24.3% (base case, 2.5%). The EAST strategy would also be favored if the annual probability of venous insufficiency was $<$7.69% (base case, 13.9%) after filter removal or $<$1.90% with a retained filter (base case, 14.1%). In initial hospitalization only, EAST guidelines were more costly by $2988 and slightly more effective by .0008 QALY, resulting in an incremental cost-effectiveness ratio of $383,638/QALY.

Conclusions: Analysis suggests prophylactic IVC filters are not cost-effective in high-risk trauma patients. The magnitude of this result is primarily dependent on probabilities of long-term sequelae (venous thromboembolism, bleeding complications). Even in the initial hospitalization, however, prophylactic IVCF costs for the additional quality-adjusted life years gained did not justify use.

The middle-arm fistula as a valuable surgical approach in patients with end-stage renal disease

Giuseppe Bonforte, Emanuela Rossi, Sara Auricchio, Daniela Pogliani, Stefano Mangano, Salvatore Mandolfo, Franco Galli, Simonetta Genovesi

Background: American and European guidelines recommend the distal radial-cephalic fistula (dRCF) as the first and best hemodialysis access in patients with end-stage renal disease (ESRD). However, this kind of arteriovenous fistula (AVF) shows a limited primary unassisted patency and frequently needs surgical revisions or angiographic procedures, or both. When dRCF is not feasible, guidelines suggest a proximal brachiocephalic AVF. The middle-arm fistula (MAF), or autogenous forearm radial-median direct access, has been suggested as a possible alternative approach. This study evaluated MAF primary unassisted patency, the most frequent causes of MAF failure, and the possible related factors.

Methods: Data on patients with a MAF placed from January 1991 until June 2008 were retrospectively collected. The probability of MAF failure overall and by the main subgroups was estimated according to Kaplan-Meier with Greenwood standard error (SE). Comparison of failure among different subgroups was performed using the log rank test in univariate analyses. The Cox regression model was used to investigate factors that independently affected the overall hazard of failure and cause-specific hazard of thrombosis.

Results: At the end of follow-up, 14.0% of MAF failed (11.6% thrombosis, 1.7% stenosis, 0.7% failed maturation), and 44.2% of MAF were still working. Cumulative probability of MAF unassisted primary patency after 4 years from the creation was 79%. Univariate analyses highlighted that women (P = .019), underweight patients (P = .010), and MAF implantation after starting hemodialysis ($P < .001$) had a higher risk of MAF failure for any cause than men, normal and overweight patients, and MAF implanted before starting hemodialysis. Results of the Cox multivariate analysis for overall MAF failure confirmed that only MAF implantation before starting hemodialysis is a protective factor against any failure (P = .003), whereas female gender (P = .016) was associated with an increase of the thrombosis hazard ratio to 2.04 (95% confidence interval, 1.14-3.63).

Conclusion: Our data demonstrate that MAF has a good unassisted primary patency and suggest that this kind of AVF could be a valuable alternative surgical approach when dRCF is not feasible in ESRD patients.